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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,116	01/17/2006	Jean Woloszko	A-22	6140

21394 7590 01/07/2010

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EXAMINER

HUPCZEY, JR, RONALD JAMES

ART UNIT

PAPER NUMBER

3739

NOTIFICATION DATE

DELIVERY MODE

01/07/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/565,116	Applicant(s) WOLOSZKO ET AL.	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-58 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 41-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-40,57 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/18/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendments and remarks, received on September 18th, 2009, has been fully considered by the examiner. Claims 1-3 and 5-58 are currently pending with claims 2-3 and 41-56 being withdrawn, claim 4 cancelled and claims 1, 5, 10, 15, 17, 19-20, 23-25, 29, 30, 33 and 35 amended. The following is a complete response to the September 18th, 2009 communication.

Specification

2. Applicant's amendment to the specification to add the "Cross Reference to Related Applications" section is acknowledged.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 37, the recitation in the claim of "a leading edge" in line 2 of the claim renders the scope of the claim indefinite. Parent claim 35 has previously set forth a leading edge on the rotating member in lines 7-8 of the claim. As such, it is unclear in the leading edge in claim 37 is the same leading edge as the leading edge in claim 35 or is directed toward a second leading edge. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 4-9, 17-26, 28-30, 33-34 and 57-58 are rejected under 35 U.S.C. 102(e) as being anticipated by West (US Pat. Pub. 2003/0163126 A1).

Regarding claim 1, West discloses an electrosurgical instrument for removing target tissue (see figures 5 and 6) comprising a shaft including a shaft distal end portion and a shaft proximal end portion (tubular member **54**), the shaft having a longitudinal void therein (see void define therein, figures 5 and 6), a tissue removal port disposed at the shaft distal end portion (opening **56**), an elongate rotating member comprising at least one leading edge (see edges on hollow shaver **58** in figures 5 and 6) housed longitudinally within the longitudinal void of the shaft (hollow shaver **58**) wherein the rotating member is capable of rotating within the shaft is coupled to a drive motor (via hollow drive shaft **60**, see paragraph [0055]) for driving rotation of the rotating member, a discrete active electrode (lead electrodes **64**) disposed along a portion of the tissue removal port perimeter (see figure 6, placement of the lead electrodes along the perimeter of the opening **56**) wherein the active electrode is capable of to electrosurgically removing at least a portion of the target tissue via molecular dissociation of target tissue components as the rotating member leading edge manipulates tissue toward the active electrode (leading edge as seen in figures 5 and 6 causing at least a portion of tissue to move closer to the leads **64**), an active electrode lead (lead wire **40** in analogous embodiment depicted in figure 4, see paragraph [0060]) extending proximally from the active electrode and disposed internal to the shaft distal end portion and a return electrode (tubular member **54**, see paragraph [0063])

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disposed at the instrument distal end. It is further noted by the Examiner that the active electrode can also be interpreted as being the tubular member **54** as described in paragraph [0063] and the return electrode being at least one of the plurality of leads **64** since the claim has only set forth intended uses for each of the electrodes in terms of one being "active" and one being a "return" and has not linked each electrode to a source of energy providing such functionality.

Regarding claim 5, West discloses the return electrode to be disposed along a second portion of the tissue removal port perimeter (see the distal end of tubular member **54** functioning as return electrode being along the perimeter of the port **56**, see paragraph [0063] and figures 5 and 6).

Regarding claim 57, West discloses the return electrode to be disposed on the shaft distal end portion such that a distance between the active electrode and the return electrode is constant (lead electrodes **64** to be fixedly spaced from tubular member **54** portion which defines return electrode).

Regarding claim 58, West discloses the tissue removal port to have a curved shape (opening **56** with curved opening, see figures 5 and 6).

Regarding claims 6 and 7, West discloses an aspiration unit including an elongate aspiration lumen in communication distally with an aspiration port and for the aspiration port to be in fluid communication with the tissue removal port (continuous aspiration pathway communicating with a opening in hollow shaver **58** and opening **56**, see paragraph [0062]).

Regarding claim 8, West discloses the device to further comprise a coagulation electrode disposed at the instrument distal end (at least one of the lead electrodes **64**).

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Regarding claim 9, West disclose the at least one of the active electrode (lead electrodes **64**) and the return electrode (tubular member **54** as defined above) to be capable of coagulating tissue or a blood vessel (see paragraphs [0043]-[0044] and [0057]).

Regarding claim 17, West discloses an electrosurgical instrument (see figures 5 and 6) for removing target tissue from a patient comprising a shaft including a shaft distal end portion and a shaft proximal end portion wherein the shaft defines a longitudinal void therein (tubular member **54** with void, see figures 5 and 6) and a tissue removal port disposed at the distal end of the port (opening **56**), an active electrode (lead electrodes **64**) disposed along a portion of the perimeter of the tissue removal port (see figure 6, placement of the lead electrodes along the perimeter of the opening **56**), a return electrode disposed on the shaft distal end portion and spaced from the active electrode (tubular sheath **54**, see paragraph [0063]), and a rotating member including a rotating distal end (hollow shaver **58**) housed longitudinally within the longitudinal void of the shaft wherein the rotating member is capable of rotating within the shaft (see figures 5 and 6) and wherein the rotating member distal end is capable of traversing the tissue removal port as the rotating member rotates within the shaft (hollow shaver **58** rotating as seen in figure 5 defines traversing the opening **56**) West further discloses the active electrode (lead electrodes **64**) capable of removing the target tissue as the rotating member distal end traverses the tissue removal port (see paragraphs [0043]-[0044] and [0057]). It is further noted by the Examiner that the active electrode can also be interpreted as being the tubular member **54** as described in paragraph [0063] and the return electrode being at least one of the plurality of leads **64** since the claim has only set forth intended uses for each of the electrodes in terms of one being "active"

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and one being a "return" and has not linked each electrode to a source of energy providing such functionality.

Regarding claim 18, West discloses the active electrode to be disposed on an external surface of the shaft distal end portion at a location adjacent to the tissue removal port (leading electrodes **64** in vicinity of opening **56**).

Regarding claim 19, West discloses the return electrode to be disposed along a second portion of the perimeter of the tissue removal port (see the distal end of tubular member **54** functioning as return electrode being along the perimeter of the port **56**, see paragraph [0063] and figures 5 and 6).

Regarding claim 20, West discloses the second portion of the perimeter is spaced from the first portion of the perimeter (first portion of the perimeter being considered adjacent to the lead electrodes **64** and second portion of the perimeter being located across the port **56**).

Regarding claim 21, West discloses the active electrode (lead electrodes **64**) to form a discrete electrode coupled to an active electrode lead (lead wire **40** in analogous embodiment depicted in figure 4, see paragraph [0060] wherein the active electrode lead extends proximally within the shaft and the active electrode lead is capable of coupling the active electrode to an electrosurgical generator (inherent to provide the disclosed electrosurgical ability).

Regarding claim 22, West discloses at least a portion of the shaft to be encased within an electrically insulating layer (insulating sheath **66**) and for the active electrode to comprise an exposed, non- insulated region of the shaft (lead electrodes **64**).

Regarding claim 23, West discloses the rotating member has a leading edge (see edges on hollow shaver **58** in figures 5 and 6) to manipulate the target tissue towards the active electrode

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as the rotating member leading edge traverses the tissue removal port (hollow shaver **58** directing at least a portion of tissue toward lead electrodes **64**).

Regarding claim 24, West discloses the active electrode to be capable of electrosurgically removing at least a portion of the target tissue via molecular dissociation of target tissue components as the target tissue is manipulated towards the active electrode (see paragraphs [0043]-[0044] and [0057]).

Regarding claim 25, West discloses the rotating member distal end to include a leading edge capable of guiding the target tissue towards the active electrode (serrated edge, curved distal portion of hollow shaver **58**, see figures 5 and 6). West further discloses the electrodes to functioning as the conducting portions of the device and does not disclose the at least the leading edge of the rotating member to conduct any electrical energy. As such, West shows that at least the leading edge of the rotating member distal end is electrically non-conducting.

Regarding claim 26, West discloses the rotating member distal end to be capable of providing friction between the rotating member and the target tissue (by cutting/abrading, see at least paragraphs [0056], [0062]).

Regarding claim 28, West discloses the device to further comprise a coagulation electrode disposed at the distal tip of the shaft (at least one of the plurality of lead electrodes **64**).

Regarding claim 29, West discloses an electrosurgical system for treating a target tissue (see figures 5 and 6) comprising an instrument which comprises a shaft including a shaft distal end portion and a shaft proximal end portion (tubular member **54** with void, see figures 5 and 6) wherein the shaft defines a longitudinal void therein, a tissue removal port at the shaft distal end portion (opening **56**), an elongate rotating member housed within the shaft and capable of

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rotating therein (hollow shaver **54**) wherein the rotating member has a distal end which traverses the tissue removal port as the rotating member rotates within the shaft (hollow shaver **58** rotating as seen in figure 5 defines traversing the opening **56**), an active electrode disposed along a portion of a perimeter of the tissue removal port (see figure 6, placement of the lead electrodes along the perimeter of the opening **56**) wherein the active electrode is capable of electrosurgically removing a portion of the target tissue during each revolution of the rotating member (see paragraphs [0043]-[0044] and [0057]) and a return electrode disposed at the instrument distal end (tubular member **54** as defined in paragraph [0063]) and an electrosurgical generator coupled to the instrument for applying a high frequency voltage between the active electrode and the return electrode (inherently coupled given the functionality disclosed in [0053], [0063], claim 8 and claim 9) wherein the active electrode is capable of electrosurgically removing at least a portion of the target tissue upon application of the high frequency voltage (see paragraphs [0043]-[0044] and [0057]). It is further noted by the Examiner that the active electrode can also be interpreted as being the tubular member **54** as described in paragraph [0063] and the return electrode being at least one of the plurality of leads **64** since the claim has only set forth intended uses for each of the electrodes in terms of one being "active" and one being a "return" and has not linked each electrode to a source of energy providing such functionality.

Regarding claim 30, West discloses the rotating member comprises a leading edge wherein the leading edge is capable of manipulating the target tissue towards the active electrode as the rotating member leading edge traverses the tissue removal port (hollow shaver **58** having a

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leading edge as in figures 5 and 6 and directing at least a portion of tissue toward lead electrodes **64**).

Regarding claim 33, West discloses the return electrode to be affixed to an external surface of the shaft distal end portion at a location adjacent to the tissue removal port (in view of the above alternate notation of claim 29 where the return in the lead electrodes **64** and the active is the shaft **54** in view of paragraph [0063], the electrodes **64** are affixed to an external surface adjacent the port **56**).

Regarding claim 34, West discloses that at least a distal portion of the rotating member has an arcuate cross-sectional shape (see distal end of hollow shaver **58**).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 10, 12, 15-16, 35-37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over West (US Pat. Pub. 2003/0163126 A1) in view of Peters (US Pat. Pub. 2002/0038122 A1).

Regarding claims 10, 35 and 36, West discloses a method for the controlled removal of a target tissue at a surgical site comprising the steps of providing an electrosurgical instrument (see figures 5 and 6), the instrument including a shaft (tubular member **54**) having a shaft distal end portion, a tissue removal port (opening **56**) disposed at the shaft distal end portion, an elongate rotating member (hollow shaver **58**) housed longitudinally within the shaft wherein the rotating member has at least one leading edge (see edges of shaver **58** in figures 5 and 6) and is capable of rotating within the shaft, a discrete active electrode (lead electrodes **64**) disposed along a portion of the perimeter of the tissue removal port (see figure 6, placement of the lead electrodes along the perimeter of the opening **56**), an active electrode lead (lead wire **40** in analogous embodiment depicted in figure 4, see paragraph [0060]) extending proximally from the active electrode and disposed internal to the shaft distal end portion and a return electrode disposed at the instrument distal end (tubular member **54**, see paragraph [0063]), positioning the instrument distal end with respect to the target tissue such that the tissue removal port lies in at least close proximity to the target tissue (see paragraphs [0022] and [0056]), rotatively driving the rotating

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member via a drive motor such that the rotating member rotates within the shaft thereby repeatedly traversing the tissue removal port to manipulate target tissue toward the active electrode (see paragraph [0055] and figures 5 and 6, leading edge as seen in figures 5 and 6 causing at least a portion of tissue to move closer to the leads **64**) and applying a high frequency voltage between the active electrode and the return electrode (see paragraph [0057] and [0059]) wherein the active electrode is capable electrosurgically removing the target tissue via molecular dissociation of target tissue components as the rotating member rotates within the shaft whereby the target tissue is sequentially removed as the rotating member distal end repeatedly traverses the tissue removal port (see paragraph [0055] and figures 5 and 6). While West discloses the selective activation of the driving and the high frequency voltage, West fails to specifically recite the simultaneous supply of high frequency voltage during the driving step. Peters discloses a similar electrosurgical instrument which provides for both a mechanical and electrosurgical treatment means. Peters additionally discloses the positioning of the device near a surgical site, the rotating of an elongate member and the application of a high frequency voltage during the rotation of the elongate member (see claim 29 and paragraph [0036]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the simultaneous activation of the high frequency voltage and the driving in order to effectuate both treatments at the same time. The simultaneous treatment allows for the user to reduce the amount of blood build-up in the surgical site by the application of the electrosurgical energy while mechanically cutting a desired a portion of tissue thereby ensuring the user is capable of clearly seeing the surgical site. Additionally, the device of West, allowing for the selective activation of both treatments, is readily useable in the combined methodology above.

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Regarding claims 12 and 39, West discloses the target tissue to comprise articular cartilage, meniscal cartilage, a ligament, or a tendon (see paragraph [0056]).

Regarding claim 15, West in view of the above rejection of claim 10 discloses that during the driving and applying steps for there to be an additional step of manipulating the instrument such that the tissue removal port is translated with respect to the target tissue (see at least paragraphs [0022] and [0056]).

Regarding claim 16, West in view of the above rejection of claim 10 discloses the driving and applying steps generate fragments of resected tissue and gaseous ablation by-products (see at least paragraphs [0022], [0056] and [0057]) and for the method to further comprises the additional step of aspirating the fragments of resected tissue and gaseous ablation by-products via an aspiration unit, wherein the aspiration unit is integral with the instrument (see paragraphs [0022],[0056] and [0057]; continuous aspiration pathway communicating with a opening in hollow shaver **58** and opening **56**, see paragraph [0062]).

Regarding claim 37, West and Peters in view of the above rejection of claim 35 discloses the rotating member distal end to include a leading edge which traverses the tissue removal port as the rotating member rotates within the shaft (serrated edge, curved distal portion of hollow shaver **58**, see figures 5 and 6). While West and Peters fail to specifically discloses that during the simultaneous driving and applying steps the active electrode functions remove the target tissue as the leading edge traverses the tissue removal port, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the active electrode, would come into contact with at least a portion of the target tissue while the elongate member is traversing the tissue removal port and the device is being positioned at the target site. It is the examiner's

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position that during such contact, at least a portion of tissue would be treated and removed due to the contact with the active electrode and the aspiration through the lumen, tissue removal port and plurality of other aspiration ports within the device of West.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over West (US Pat. Pub. 2003/0163126 A1) in view of Peters (US Pat. Pub. 2002/0038122 A1) as applied to claim 10 above, and further in view of Bonnell et al (US Pat. 4,203,444).

Regarding claim 11, West and Peters fails to disclose the positioning at the target site to comprise positioning the shaft distal end portion at or within a synovial joint of the patient. Bonnell discloses a similar device to that of West and Peters and discloses for the device to be inserted to a treatment site which specifically consists of a synovial joint of the patient (see col. 1; 63 – col. 2; 26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to insert the combined device of West and Peters into the synovial joint of a patient in order to provide for a minimally invasive method of treating/removing target tissue therein. Such treatment of a synovial joint, as evidenced by Bonnell reduces the healing time, trauma and chance of complication experienced with normal open methods of surgery.

12. Claims 13 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over West (US Pat. Pub. 2003/0163126 A1) in view of Peters (US Pat. Pub. 2002/0038122 A1) as applied to claims 10 and 35 respectively above, and further in view of Woloszko et al (US Pat. Pub. 2001/0025177 A1).

Regarding claims 13 and 40, West and Peters fail to specifically recite the high frequency voltage applied to being the range of from about 200 volts RMS to 1500 volts RMS. Woloszko discloses a similar electrosurgical device functioning to provide the treatment of a target portion

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of tissue via the application of high frequency voltage. Woloszko further disclose the voltage to be applied within a range of 5 to 1000 volts RMS. While not specifically reciting the complete claimed range of 200 to 1500 volts RMS, it would have been obvious to one having ordinary skill in the art at the time the invention was made to supply high frequency voltage within such a range since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Additionally, applicant has failed to set forth any criticality or unexpected result which would render such an operating range as a non-obvious variant.

13. Claims 14 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over West (US Pat. Pub. 2003/0163126 A1) in view of Peters (US Pat. Pub. 2002/0038122 A1) as applied to claims 10 and 35 respectively above, and further in view of Miller (US Pat. No. 5,423,844).

Regarding claims 14 and 38, West and Peters fail to specifically recite the driving to comprise rotating the rotating member at a speed in the range of from about 20 rpm to 90 rpm. Miller discloses a similar device to that of West and Peters and further discloses the device to drive the rotating elongate member in a range from 60 rpm to 2000 rpm (see col. 6; 19-31). While not specifically reciting the complete claimed range of 20 rpm to 90 rpm, it would have been obvious to one having ordinary skill in the art at the time the invention was made to drive the elongate member within such a range since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Additionally, applicant has failed to set forth any criticality or unexpected result which would render such an operating range as a non-obvious variant.

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14. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over West (US Pat. Pub. 2003/0163126 A1) as applied to claim 17 above, and further in view of Miller (US Pat. No. 5,423,844).

Regarding claims 27, West discloses the rotating member to be coupled to a drive motor for driving rotation of the rotating member within the shaft at a speed in the range of from about 20 rpm to 90 rpm. Miller discloses a similar device to that of West and further discloses the device to drive the rotating elongate member in a range from 60 rpm to 2000 rpm (see col. 6; 19-31). While not specifically reciting the complete claimed range of 20 rpm to 90 rpm, it would have been obvious to one having ordinary skill in the art at the time the invention was made to drive the elongate member within such a range since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Additionally, applicant has failed to set forth any criticality or unexpected result which would render such an operating range as a non-obvious variant.

15. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over West (US Pat. Pub. 2003/0163126 A1) as applied to claim 29 above, and further in view of Savage et al (US Pat. No. 6,032,673).

Regarding claim 31, West fails to specifically disclose for the rotating member to be coupled to the drive motor via a flexible transmission line for driving rotation of the rotating member within the shaft. Savage discloses a similar electrosurgical device for treating a target portion of tissue. Savage further discloses a drive motor (drive motor **348**) to be couple to rotating portion by a flexible transmission line (flex drive input **336**, see col. 20; 47 - col. 21; 2).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the flexible transmission line as that of Savage to interconnect the drive motor and elongate member of West. Such a provision of a flexible drive line allows for drive motor to be located remote from the device thereby reducing the size of the instrument and increasing the maneuverability of the device by the user.

Regarding claim 32, both West and Savage (drive motor **348**, power unit **346**) disclose the claimed invention except for the drive motor to be integral with the electrosurgical generator. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to integrate the drive motor and the electrosurgical generator into one electrical assembly, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893). Additionally, it is well known in the art to integrate a plurality of sources and drives (i.e. ultrasonic, fluid, vacuum) with an electrosurgical generator to provide for a combined unit for connecting with a multi-functional instrument.

Response to Arguments

16. Applicant's arguments filed September 18th, 2009 have been fully considered but they are not persuasive.

In response to Applicant's argument throughout the remarks that West (US Pat. Pub. 2003/01631260) fails to anticipate or fairly suggest an active electrode disposed along a portion of the tissue removal port perimeter, the Examiner respectfully disagrees. While Applicant has amended the claims to more clearly relate the position of the active electrode in relation to the tissue removal port, it is the Examiner's position that in the broadest reasonable interpretation of

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the claim language presented West still anticipates the limitation of "an active electrode disposed along a portion of the perimeter of the tissue removal port". In looking at the disclosure and specifically figures 5 and 6 of West, it is the Examiner's position that the close proximity of the leads **64** to the port **56** constitutes the electrode being "along a portion of the perimeter" with the "perimeter" being looked at as the boundary of the port **56** define by the outer edge of the shaft **54** and "along" being taken as in view of its plain definition of "at a point or points on" (taken from <http://www.merriam-webster.com/dictionary/along> under definition number 1). It is noted that the leads **64** are not located on a portion of the perimeter or interior to a portion of the perimeter.

The Examiner has also above proffered a secondary interpretation of the active and return electrode. It is the Examiner's position the shaft **54** functioning to receive electrosurgical energy can be defined as the active electrode since Applicant has failed to attach the electrode to any source of energy requiring a certain function of the electrode. In taking the shaft **54** as the active and at least one of the leads **64** as the return electrode, the Examiner's believes that this interpretation anticipates the newly added limitations. Shaft **54** functioning as the active electrode and defining the tissue removal port **56** would render the active electrode being along at least of portion of the tissue removal port perimeter and would also anticipate the active electrode being on or interior to a portion of the perimeter.

It is therefore the Examiner's position that West adequately anticipates the newly added limitations and that each of the proffered rejections above either anticipate or fairly suggest the claims limitations presented.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Ronald J. Hupczey/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH